REMARKS

Claims 1-8 and 11-14 were pending in the present application. Claims 1-7, 11 and 12 were rejected. Claims 1 and 14 are herein amended. Claims 2-6 and 11-13 are herein cancelled without prejudice.

Election/Restriction

It is the position of the Office Action that claims 13 and 14 are directed to an invention that is independent or distinct from the invention originally claimed. The Office Action notes that Applicants previously elected Arg-Gly-Asp as (X), Gly-Ala-Gly-Ala-Gly-Ser as (Y), and polyalkylenepolyamine as (A). Additionally, the Office Action states that the recitation of specific peptides by trademark names (such as ProNectin F, ProNectin F2, etc.) "lacks antecedent basis in the base claim." This statement is confusing, since (a) antecedent basis is not needed for the first mentioning of a claim term, and (b) the issue of antecedent basis is a matter for a rejection based on 35 U.S.C. §112, second paragraph. As a result of the above, the Office Action states that the originally presented invention was constructively elected, and that claims 13 and 14 are withdrawn from consideration.

In response, Applicants respectfully submit that claims 13 and 14 do in fact recite elected subject matter. As explained on page 9, lines 4-11, ProNectin F is a peptide having Arg-Gly-Asp as (X) and $(Gly\text{-}Ala\text{-}Gly\text{-}Ala\text{-}Gly\text{-}Ser)_9$ as (Y). In ProNectin F, these sequences are chemically bonded to each other in an alternating fashion. In other words, ProNectin F is a specific embodiment of the subject matter of the polypeptide of claim 1 prior to the amendment herein.

Thus, claims 13 and 14 recited elected subject matter. In fact, these claims recited narrower subject matter than claims 11 and 12, each of which were examined on the merits.

At this time, Applicants herein cancel claim 13 and incorporate its subject matter into claim 1. Applicants respectfully submit that this subject matter is contained within the subject matter already under examination in claim 1. Similarly, Applicants respectfully request that claim 14 be examined on the merits, since it recites elected subject matter. However, Applicants' note that in order to comply with the requirements of 35 U.S.C. §112, and to put the claims in better condition for allowance, Applicants remove the "ProNectin" tradenames, and instead recite the structures of these polypeptides, which are described on page 9 of the specification. The Markush group of polypeptides listed in claim 1 are, in order, ProNectin F, ProNectin F2, ProNectin F3, ProNectin L, ProNectin L2, ProNectin L3, ProNectin Y, ProNectin Y2 and ProNectin Y3.

Applicants' Response to Claim Rejections under 35 U.S.C. §112

Claims 2 and 3 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that there is insufficient antecedent basis for the term "repeated" in claims 2 and 3. Applicants herein cancel claims 2 and 3. Thus, this rejection is moot.

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

It is the position of the Office Action that claims 1-7 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. It appears that the Office Action identifies two issues with the claims: (i) that the specification does not support the numerous species encompassed by the claims, and (ii) that the claims encompass unknown structural features.

It is accurate to state that the specification does not identify a full length sequence of polypeptide (P). As a preliminary matter, Applicants note that the claimed polypeptides (P) of claim 1 are herein amended to be those corresponding to ProNectin F, F2, F3, L, L2, L3, Y, Y2 or Y3, as described on page 9 of the specification. Thus, the number of species encompassed by the claims has been significantly reduced.

Additionally, Applicants respectfully submit that a full length polypeptide sequence is not required in order to comply with 35 U.S.C. §112, first paragraph. Rather, where such disclosure is a sufficient disclosure, only a partial structure need be disclosed. "An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and

structure, or some combination of such characteristics. *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613." MPEP §2163 (emphasis added).

As to whether the claims encompass unknown structural features, Applicants note that the Office Action ***again*** misquotes the specification, and partially relies on this misquotation as a basis for the written description rejection. Specifically, the Office Action alleges that ProNectin F is described on page 24 as:

> "ProNectin F (product of Sanyo Chemical Industries, Ltd.) which contains the Arg Gly Asp (RGD) sequence (SEQ ID NO: 1) and the (Gly Ala Gly Ala Gly Ser)$_9$ sequence (SEQ ID NO: 8) each in the number of about 13 and has a Mw of about ***110,000 d***" (emphasis added).

The Office Action states that the composition of ProNectin and the molecular weight disclosed "indicates that the polypeptide in each case is not just limited to the composition of the peptides (X) and (Y) and contains unknown structural features that is [*sic*] neither well defined in the specification or recited in the claims."

However, this passage actually reads as follows:

> "ProNectin F (product of Sanyo Chemical Industries, Ltd.) which contains the Arg Gly Asp (RGD) sequence (1) and the (Gly Ala Gly Ala Gly Ser)$_9$ sequence (8) each in the number of about 13 and has a Mw of about ***110,000***" (emphasis added)

As is clear by review of the passage at page 24, lines 18-22 and a similar passage at page 9, lines 4-11, the molecular weight of ProNectin F is NOT measured in Daltons. As previously explained in the February 13, 2008 filing, weight average molecular weight (Mw) in this application is measured by the SDS-PAGE method. Applicants respectfully request that the specification be accurately cited in future Office Actions.

As to ProNectins such as ProNectin F, the (X) and (Y) sequences are indirectly bound with intervening amino acids as shown in the following formula:

$$\sim X \sim Y \sim X \sim Y \sim$$

In this formula, "~" represents an amino acid sequence other than X and Y. Thus, for ProNectin F, polypeptide (P) is:

$$\sim [\text{Arg Gly Asp} \sim (\text{Gly Ala Gly Ala Gly Ser})_9 \sim]^{13}$$

However, even if ProNectin F, or any other claimed polypeptide (P), contained undisclosed structural features in the form of other amino acids, it is unnecessary to disclose this in order to comply with the written description requirement, since the partial structure is sufficient, as explained above.

On a related point, the Office Action's statement on page 7 appears to illustrate confusion regarding the specification. The Office Action states that "Even the polypeptide SEQ ID NO: 49 that represents ProNectin F3 according to Example 3 only exhibits sequence corresponding to the auxiliary sequences (Y) and part of the sequence corresponds to "X"." Applicants respectfully clarify that SEQ ID NO: 49 is not ProNectin F3. Rather, ProNectin F3 includes SEQ ID NO: 1 and SEQ ID NO: 49, as shown on page 9, lines 18-23. For ProNectin F3, SEQ ID NO: 1 is repeated three times, SEQ ID NO: 49 is repeated three times, SEQ ID NO: 1 is repeated three times, and so forth. In view of the above, Applicants respectfully submit that the pending claims fully comply with 35 U.S.C. §112. Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Rejections under 35 U.S.C. §103

Claims 1-7, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ferrari et al. (U.S. Patent No. 6,184,348) in view of Cook et al. (U.S. Patent No. 5,916,585) and Lin et al. (Journal of Biomedical Material Research, 28, 329-342, 1994).

It is the position of the Office Action that Ferrari discloses the invention as claimed, with the exception of (i) the use of polyalkylenepolyamine or polyarylenepolyamine matrices and (ii) covalent bonding between the peptide and the polymer sheet. The Office Action relies on Cook to provide the teaching of (i) the use of polyalkylenepolyamine or polyarylenepolyamine matrices. The Office Action relies on Lin to provide the teaching of (ii) attaching the polypeptide to the polymer sheet by covalent bonding.

Ferrari relates to a recombinantly produced proteinaceous polymer composition. As the Office Action recognizes, Ferrari does not teach the use of a polyalkylenepolyamine and/or polyarylenepolyamine. Moreover, Ferrari describes that the "subject material may be made into or coated on woven fabrics, films or membranes," as recognized by the Office Action. However, Ferrari does not describe the kinds of films or membranes or even suggest polyurethane as a sheet. Furthermore, as recognized by the Office Action, Ferrari does not disclose that a polypeptide and a sheet are bonded by a covalent bonding. In addition, Ferrari does not disclose that acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using the wound dressing having the claimed constitution.

Cook relates to a biodegradable material for immobilization of bioactive species thereon, the material comprising a porous hydrophobic biodegradable support member and a first layer

comprised of at least one species of a polymeric surfactant, and wherein the surfactant is cross-linked to itself with a cross-linking agent. Cook discloses that the bioactive species are immobilized directly to chemical functional groups of the first layer as shown in the Figures. Namely, the bioactive species are immobilized not to the hydrophobic support member, but to the first layer comprised of a surfactant. Thus, as the Office Action recognizes, Cook does not disclose that the bioactive species and the hydrophobic support member are bonded by a covalent bonding. Moreover, Cook does not disclose that acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using the wound dressing of the present invention having the above specific constitution.

Lin only describes the synthesis, surface and cell-adhesion properties of polyurethane containing covalently graft RGD-peptides. In Lin, the RGD-containing peptide is merely grafted to the polymer backbone. Namely, Lin does not disclose the wound dressing of the claimed embodiments in which the polypeptide (P) and the polyurethane sheet (S) are bonded by covalent bonding. Lin only describes RGD-peptides and does not disclose the polypeptide (P) having the recited ProNectins.

Applicants respectfully submit that the disclosure of Cook is insufficient. Cook merely identifies polyethyleneimine as one of many polymeric surfactants. Additionally, the Office Action cites Cook's reference to RGD at column 6, line 60. However, in this passage, RGD is only listed as one of many possible targets of immobilization. Applicants respectfully submit that Cook's disclosure of polyethyleneimine and RGD are not a sufficient disclosure.

Although a reference is prior art for all that it teaches, Applicants respectfully submit that the teachings of Cook are limited to an invitation to investigate. Specifically, Applicants respectfully submit that the listing of over 18 possible polymeric surfactants and dozens of immobilization targets in Cook is not an enabling disclosure, but merely an invitation to investigate. According to MPEP §2121.01, "[t]he disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation."

Cook does not provide guidance as to which of these polymeric surfactants or immobilization targets is likely to be effective. Instead, Cook is merely an invitation to investigate these polymeric surfactants and immobilization targets. According to MPEP §2112, "'[a]n invitation to investigate is not an inherent disclosure' where a prior art reference 'discloses no more than a broad genus of potential applications of its discoveries'" (Quoting *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004). The disclosure of Cook of treatment of dozens of broad classes of diseases is merely a broad disclosure of potential applications, and not an enabling disclosure. Therefore, for at least these reasons, Applicants respectfully submit that Cook does not provide a sufficient disclosure of the recited polyamines (A).

In addition, Applicants respectfully submit that the experimental data in the present specification provides evidence for unexpected results by using the specific polyamine (A) such as polyethyleneimine, as compared with other surfactants such as poly-lysine. The Examples,

Comparative Examples (especially wound dressings HB3-HB6) and Table 1 on page 34 of the specification show that the specific polyamine (A) provides unexpected results as compared with other compounds such as poly-L-lysine and poly(dimethylamino ethyl methacrylate).

Accordingly, even if Ferrari, Cook and Lin are combined, the combination of references does not disclose or suggest that the unexpected excellent results of the acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using a wound dressing having the claimed constitution. Therefore, the covalent bonding of the peptide with the matrix is not "the product not of innovation but of ordinary skill and common sense." As such, the claimed embodiments would not have been obvious to one having ordinary skill in the art from the cited references. Favorable reconsideration is respectfully requested.

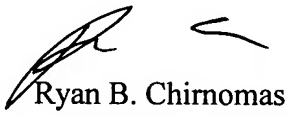
For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/nrp